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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,876	11/29/2007	John Pedersen	742111-172	7080

25570 7590 06/24/2011  
ROBERTS MLOTKOWSKI SAFRAN & COLE, P.C.  
Intellectual Property Department  
P.O. Box 10064  
MCLEAN, VA 22102-8064

EXAMINER
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EDWARDS, LYDIA E

ART UNIT	PAPER NUMBER
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1775

NOTIFICATION DATE	DELIVERY MODE
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06/24/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/573,876	<b>Applicant(s)</b> PEDERSEN, JOHN	
	<b>Examiner</b> LYDIA EDWARDS	<b>Art Unit</b> 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/29/2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/29/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/29/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 19 recites “a mechanical bending stop” however; the specification does not provide sufficient support for the instant limitation.

### ***Claim Objections***

Claims 16 -18 are objected to because of the following informalities:

Claim 16 is a dependent claim which is drawn to a container however; the independent claim 1 is drawn to a tissue bath system.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US 5700688).

Regarding Claim 1, Lee et al. ('688) discloses a tissue bath system with at least one sample container [14] and at least one sample holder [19] for holding at least one tissue sample [3] inside a tissue medium in the at least one container, the at least one sample holder being connected to at least one force transducer [24] for measuring force exerted on the at least one holder by contraction of the at least one tissue sample upon stimulation, the system further comprising a temperature regulation system [8] for regulating the temperature of the tissue

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medium in the at least one sample container, characterized in, that the system comprises a container station with at least one chamber for placement of at least one sample container in the at least one chamber [12] (Col 6, line 59-Col 7, line 30).

Regarding Claim 19, Lee et al. ('688) discloses wherein the transducer [24] is mounted in a housing [2], the housing constructed with a mechanical bending stop [26]. The examiner interprets the variable differential transformer [26] to be equivalent to that of a mechanical bending stop.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5700688).

Regarding Claim 2, Lee et al. ('688) does not disclose a plurality of chambers. He does however disclose one chamber [12].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lee et al. with a plurality of chambers since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cannon et al. (US 20020146817) in view of Lee et al. (US 5700688).

Regarding Claims 1-2 and 13, Cannon et al. ('817) discloses an automated bioculture system with at least one biochamber (sample container) [104] and an actuator and fixed surface (sample holder) [101 and 103] for holding at least one cell or tissue sample [105] media flows through the biochamber in a direction represent by arrows [98], the movement of the actuator against the biochamber can provide compressive forces [107]; the system further comprising a temperature regulation system (See Paragraphs 80-85) for regulating the temperature of the tissue medium in the at least one sample container, characterized in, that the system comprises a docking station or incubator rack (container station) [2] with at least one chamber (See Paragraphs 43-46) for placement of at least one a cartridge (sample container) [1] in the at least one chamber [12].

Cannon et al. does not disclose a force transducer for measuring force exerted on the at least one holder by contraction of the at least one tissue sample upon stimulation.

Lee et al. ('688) discloses the use of a force transducer or load cells [24] means for determining the force generated by the oriented tissue-equivalent, are connected to actuator [20] and the shafts [18] of the loading chamber (See Col 6, line 59-Col 7, line 24; Figure 3).

It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify Cannon et al. with a force transducer as taught by Lee et al. in order to provide a

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means to determine the mechanical properties of an oriented tissue-equivalent which can be used to replace damaged connective tissue such as ligaments or tendons.

Regarding Claim 3, Cannon et al. ('817) discloses an automated bioculture system comprising a cartridge (container) [1] has a sample reservoir [10] and a fluid channel [11] extending from the reservoir and traversing a wall of the Container, wherein the docking station or rack (container station) [2] comprises a plurality of placement sections configured for placement of a sample container in each placement section (See Figure 4 and Paragraph 46), wherein each placement section has a fluid transport unit [4, 11, 23, 28, 41 and 43] configured for coupling to the fluid channel of the container for transport of fluid through the fluid channel when the container is placed in the placement section (See Figures 3 and 5-8; Paragraphs 44-45, 50-54 and 58).

Regarding Claims 4 and 16, Cannon et al. ('817) discloses wherein the fluid channel is in the lower part of a side wall of the container or in the bottom of the container (See Figures 3 and 6).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the fluid channel in the lower part of the wall of the container, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding Claim 5, Cannon et al. ('817) discloses wherein the fluid transport unit comprises a solution supply tube [11] for regulated supply of solution to the reservoir (See Figures 3 and 6-8).

Regarding Claim 6, Cannon et al. ('817) discloses wherein the fluid transport unit comprises a gas supply [40] for regulated supply of gas to the reservoir (See Paragraph 54).

Regarding Claim 7, Cannon et al. ('817) discloses wherein oxygenator [24] may be formed of gas permeable silicon or similar tubing. He also teaches wherein the oxygenator may

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alternately be a membrane positioned over a biochamber, valve, or another component (gas supply 40) in the flowpath (See Paragraph 60). The examiner deems the flowpath capable of extending into the reservoir.

Regarding Claim 8, Cannon et al. ('817) discloses wherein the fluid transport unit comprises a liquid discharge tube for discharge of liquid from the reservoir (See Paragraph 51).

Regarding Claim 9, Cannon et al. ('817) discloses wherein each of the at least one chamber has an air inlet [36 and 38] that is configured to regulate the flow of air through the air inlet (See paragraph 54).

Regarding Claims 10 and 17, Cannon et al. ('817) discloses a sampling interface [28] of which the examiner deems to be equivalent to an overflow tube (See Paragraph 51 and Figure 5).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate overflow tube in the upper part of the reservoir, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding Claim 11, Cannon et al. ('817) discloses wherein the container has a cylindrical fluid channel extending from the container, and wherein the fluid transport unit comprises a corresponding adapter for sealing engagement [41 and 43] around the fluid channel (See Paragraph 53).

Regarding Claim 12, Cannon et al. ('817) discloses wherein the container station for each placement section has a sensor configured to determine whether a container has been placed in the placement section or not (paragraph 48).

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Regarding Claim 14, Cannon et al. ('817) discloses wherein the container station has at least one receptacle for receiving a solution tank, where the solution tank via a tubing system and a solution flow control valve [30, 34-35] is connected to the fluid transport unit (See Paragraphs 52-53 and Figures 6-8).

Regarding Claims 15 and 18, Cannon et al. ('817) discloses wherein the reservoirs of a plurality of containers have identical heights (See Figures 1-4) but he does not disclose at least two of the containers have reservoirs with different widths in order to have different volumes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the size of the reservoirs as an obvious matter of design choice, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571.272.1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael A Marcheschi/  
Supervisory Patent Examiner, Art Unit 1775

/LYDIA EDWARDS/  
Examiner  
Art Unit 1775

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